

AUG - 8 1996

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K960765

Submitted By:

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Device Name

Proprietary Name: MENTOR® Advent™ A/B System

Common Name: A-B Scanner

Classification Name: Ultrasonic System, Imaging, Ophthalmic (86 HPR)

Substantial Equivalence Claim

The substantial equivalence device selected for comparison to this device is Teknar A/B III. Its 510(k) control number is K871536.

Device Description

MENTOR® Advent™ A/B System is an easy to use ophthalmic ultrasonic system, offering capabilities and versatility for both A-scan and B-scan operations.

The A-Scan biometric unit of the Advent System has the following features:

- Operational modes - Automatic and Manual
- Probe alignment - LED fixation light and audio feedback
- Multiple eye categories - Normal, Aphakic, Cataractous, Dense Cataractous and Pseudophakic
- IOL calculations - programs include the latest in SRK, Holladay and Hoffer Q
- Patient storage - up to 16 patients, including right and left eye
- User interface - standard computer keyboard
- Display - 9" high resolution white phosphor CRT
- Accessories - printer, video output

The B-Scan imaging unit of the Advent System has the following features:

- Scanning - 50 degrees sector scan probe, allowing eye view from wide variety of angles
- Normal mode - requires selection of parameters
- Windowed mode - allows user selectable scanning angle
- Controls - depth, gain, contrast and brightness
- Display - 9" high resolution white phosphor CRT
- User interface - standard computer keyboard
- Accessories - camera, printer, VCR

MENTOR® Advent™ System uses the following transducer operations and characteristics:

A-Scan: There is a single ultrasound mode where the transducer is pulsed at a repetition frequency of approximately 5 Hz. The transducer is a non-scanning crystal with a frequency of approximately 8 Mhz. This system uses the same ultrasound transducer as in the predicate device.

B-Scan: There are two ultrasound modes, Normal and Windowed. The transducer is a single crystal mechanical sector probe with a center frequency of 11 MHz. It is housed in an oil-filled sealed chamber. The transducer sweeps 8 frames/sec. Sweep angle is 50°, pulse repetition frequency is 5.5 KHz and there are 275 transmitted lines per scan. In the Windowed mode, the size and position of the user selected window affects the pulse rate and spacing of the pulse, and thus the radiated field. Ultrasonic power measurements reported later have been made in the worst case condition.

Intended Use

MENTOR® Advent™ A/B System is a dual function ultrasonic ophthalmic imaging system. The A-scan is used to measure the axial length of the eye. The system includes various programs for calculating the optical power of the IOL to be implanted during cataract surgery. Anterior chamber depth and lens thickness of the eye are also measured and displayed. The B-scan is used to image the internal structure of the eye including the opaque media and posterior pathology for the purpose of diagnosing pathological or traumatic conditions in the eye.

Substantial Equivalence Comparison

	MENTOR® Advent™ A/B System	Teknar A/B III
Indication	The A-scan is used to measure the axial length of the eye. The system includes various programs for calculating the optical power of the IOL to be implanted during cataract surgery. Anterior chamber depth and lens thickness of the eye are also measured and displayed. The B-scan is used to image the internal structure of the eye including opaque media and posterior pathology for the purpose of diagnosing pathological or traumatic conditions in the eye.	Same
Transducer/Probe Design		
A-Scan:	Non-scanning crystal, 8 MHz frequency, transducer in direct contact with eye surface.	Same
B-Scan:	Single crystal mechanical sector probe with 11 MHz center frequency focused at 25 mm. Housed in an oil-filled sealed chamber. 8 frames per sec. sweep, 50° sector scan.	Single crystal mechanical sector probe with 10 MHz center frequency focused at 18 mm. Housed in an oil-filled sealed chamber. 15 frames per sec. sweep, 50° sector scan.
Probe Physicals		
A-Scan:	Weight - 5 oz., Length - 3.875", Diameter - 0.40".	Same
B-Scan:	Weight - 1.7 oz., Length - 4.75", Diameter - 0.625".	Weight - 2.6 oz., Length - 6.00", Diameter - 0.625".
Scanning Mode		
A-Scan:	Automatic & Manual	Automatic, Manual & Diagnostic
B-Scan:	Normal and Windowed	Normal
A-Scan Eye Categories	Normal, Aphakic, Cataractous, Dense Cataractous and Pseudophakic.	Same
A-Scan IOL Calculations	Software programs for SRK, Holladay and Hoffer Q calculations.	Same
A-Scan Initialized Velocity	1532 m/sec - vitreous and aqueous 1642 m/sec - normal lens 1629 m/sec - cataractous lens	Same
A-Scan Probe Alignment	LED fixation light and audio feedback.	Same

	MENTOR® Advent™ A/B System	Teknar A/B III
B-Scan Controls	Depth, gain, contrast and brightness.	Same
B-Scan Depth	20/50/70 mm	50/70 mm
B-Scan Scale	Calibrated to 1550 meters/sec.	Same

The determination of substantial equivalence is not based on an assessment of any performance data, clinical or non-clinical.


Submitter's Signature

2-15-96
Date